



U.S. Environmental Protection Agency

Tracking Progress on U.S. EPA's Polybrominated Diphenyl Ethers (PBDEs) Project Plan: Status Report on Key Activities

EPA Polybrominated Diphenyl Ethers Workgroup
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In March 2006, EPA released its Polybrominated Diphenyl Ethers (PBDEs) Project Plan. The Project Plan outlines EPA's activities regarding PBDEs, a group of brominated flame retardant chemicals. The Project Plan identifies four major objectives:

1. Assess Substitutes for Pentabromodiphenyl Ether and Octabromodiphenyl Ether
2. Assess and Evaluate Decabromodiphenyl Ether
3. Assess Risks of Pentabromodiphenyl Ether and Octabromodiphenyl Ether
4. Track Developments Concerning Other Brominated Flame Retardants of Interest

The Project Plan presents EPA's key activities for each of these objectives. In this Status Report, EPA presents information on progress through early 2008 for each of the activities in the Project Plan. This is the second such report; the first status report was released in March 2007. EPA will update this status report annually; the current status report can be found online, along with the PBDEs Project Plan, at <http://www.epa.gov/oppt/pbde/>.

Status of Activities Under Objective 1: Assess Substitutes for Pentabromodiphenyl Ether and Octabromodiphenyl Ether

Activity 1.1

Text of March 2006 Project Plan

“EPA has formed a Furniture Flame Retardancy Partnership with several industry associations and other stakeholders. The Partnership has conducted a screening level hazard assessment of flame retardant chemicals that may be suitable substitutes for pentaBDE. For each alternative chemical, the available scientific studies have been reviewed and summarized, data gaps identified, and environmental and human health effect endpoints characterized. This screening assessment was completed in September 2005 and is available at <http://www.epa.gov/opptintr/dfc/pubs/projects/flameret/index.htm>. The information in this report will help furniture manufacturers incorporate health and environmental considerations into their selection of replacements for pentaBDE.”

Current Status

This activity has been completed. The final product is publicly available (see URL above).

Next Steps

None.

Activity 1.2

Text of March 2006 Project Plan

“EPA will work with the Furniture Flame Retardancy Partnership to review additional data on flame retardant chemicals used in furniture as appropriate.”

Current Status

The Partnership recently considered options for identifying any new hazard data on chemicals used as pentaBDE replacements and determined that necessary drivers for updating the table, including industry and NGO demand for further data, are not present.

Next Steps

Update table of hazard data for pentaBDE alternatives (Table 4-1 of screening assessment report, see Activity 1.1) if demand increases.

Activity 1.3

Text of March 2006 Project Plan

“EPA will monitor developments in the market for replacing octaBDE and will assess octaBDE substitutes if warranted.”

Current Status

Currently there is no formal assessment of alternatives to octaBDE ongoing at EPA. However, the Agency continues to monitor information on alternatives to octaBDE during participation as an Observer (i.e., not a Party) in the review and development of risk management evaluations and listing options for octaBDE under both the LRTAP POPs Protocol and the Stockholm Convention.

Next Steps

EPA will continue to monitor information collection and risk management policy development for octaBDE in international forums.

Status of Activities Under Objective 2: Assess and Evaluate Decabromodiphenyl Ether

Activity 2.1

Text of March 2006 Project Plan

“EPA is conducting a review of the available toxicology data for decaBDE, and will update the decaBDE assessment in EPA’s IRIS database. Completion of this assessment is projected for 2006.”

Current Status

The Integrated Risk Information System (IRIS) Toxicological Review of Decabromodiphenyl Ether (BDE-209) was released for public comment in December 2006, and is available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=161848>. External peer review of the Toxicological Review has been completed, and the document is currently undergoing final revisions.

Next Steps

The final assessment document is projected to be available on the IRIS website in Spring 2008.

Activity 2.2

Text of March 2006 Project Plan

“EPA will monitor ongoing and planned research on the toxicity of decaBDE and its metabolites. Of particular interest are a developmental neurotoxicity study of decaBDE that is being sponsored by the European Union, and studies conducted by the FIRE project (Flame retardants Integrated Risk assessment for Endocrine effects; see www.rivm.nl/fire) in Europe. FIRE is conducting 28-day toxicity study in rats, and may follow this with other animal studies. EPA will coordinate with the EU and the FIRE project to ensure that all relevant information regarding decaBDE toxicology is shared in a timely manner.”

Current Status

For the European Union effort, preliminary toxicokinetic studies comparing different routes of administration and different dosing vehicles were conducted in 2006-2007. The developmental neurotoxicity study, conducted in rats, was commenced in December 2007. In addition, a separate study of decaBDE developmental neurotoxicity in mice has been published (Rice et al., Neurotoxicology and Teratology 2007).

The FIRE project has been completed, including the 28-day study of decaBDE in rats, and a summary report has been prepared.

Next Steps

EPA will continue to track the availability of new toxicology data on decaBDE, and will review reports and articles when they are published.

Activity 2.3

Text of March 2006 Project Plan

“EPA will further investigate the environmental fate and metabolism of decaBDE, including the potential for formation of lower-brominated congeners by debromination of decaBDE in the environment. Through its VCCEP program, EPA has determined that additional data are needed to address the potential of decaBDE to degrade to other substances in the environment. EPA will work with the industry sponsors of the decaBDE VCCEP assessment to address this data need.”

Note - Data needs were identified as: anaerobic debromination in aquatic sediments and sludge digesters; photolysis in the indoor environment; rate of release from sources in the indoor environment; and migration from land-disposed goods, and subsequent anaerobic biodegradation under landfill conditions.

Current Status

The industry sponsor committed to conducting a Tier 2 VCCEP assessment for decaBDE in December 2005. EPA understands that the industry sponsor has concluded that it can adequately characterize the risk to children from exposure to decaBDE without conducting the additional testing requested in EPA’s Data Needs Decision Letter of August 2005. The industry sponsor recently submitted an updated VCCEP document, and EPA is currently reviewing this document to determine if it satisfies the Agency's previously expressed data needs.

Next Steps

EPA will review the industry sponsor’s document. New documents will be posted on the Voluntary Children’s Chemical Evaluation Program website as they become available, at <http://www.epa.gov/oppt/vccep/pubs/chem21.htm>.

Activity 2.4

Text of March 2006 Project Plan

“EPA will prepare a white paper that reviews the available information on the environmental fate of decaBDE. The purpose of this paper is to assess the potential for debromination of decaBDE through various natural mechanisms (e.g. exposure to light, breakdown via metabolism in living organisms), the rate, extent and conditions under which debromination may occur, and whether debromination of decaBDE is likely to be a significant source of lower-brominated PBDEs in humans and wildlife. The white paper will also identify additional studies that would be helpful to

developing a better understanding of the environmental fate of decaBDE. Emerging information currently under development and anticipated over the coming year will be an important part of this evaluation, including data needs identified through VCCEP. This effort will be initiated in 2006, and the white paper will be peer reviewed in accordance with EPA's *Peer Review Handbook* and the Office of Management and Budget's *Final Information Quality Bulletin for Peer Review*."

Current Status

These topics will be addressed as part of a report on assessing exposure to PBDEs, being prepared by EPA's National Center for Environmental Assessment (NCEA).

The chapters are:

- 1 – Introduction
- 2 – Production and Use
- 3 – Environmental Fate
- 4 – Environmental and Exposure Media Concentrations
- 5 – Human Exposure.

Chapter 3 most directly addresses the subject of this White Paper as proposed in the Project Plan.

Next Steps

A completed draft document, including all 5 chapters, is expected to be circulated for internal EPA review in Spring 2008. Chapter 3 on Environmental Fate will include extensive text on decaBDE debromination and other critical environmental fate pathways, along with environmental fate information on the other PBDEs.

Following internal review and clearance, EPA will initiate an external review with the intent to finalize and publish this as an EPA report. The goal is to finalize and release the document by the end of 2008.

Activity 2.5

Text of March 2006 Project Plan

"EPA will conduct an interim review of all available scientific information concerning decaBDE in 2006/2007. The information to be considered in this review will include CDC NHANES data on decaBDE body burdens in the U.S. population, other studies reporting decaBDE body burdens in the U.S., data from EPA's National Lake Fish Tissue Study, the EPA White Paper on environmental fate of decaBDE, information developed under VCCEP, and other studies that may become available concerning decaBDE toxicology and environmental fate (including studies conducted or funded by EPA and other agencies listed in Appendices C and D). Based on this interim review, EPA will consider whether the information warrants pursuing additional research, risk assessment or regulation using existing legal authorities."

Current Status

EPA has continued gathering and reviewing information on decaBDE (see Activities 2.1 – 2.4 above).

Next Steps

EPA will continue reviewing information on decaBDE as it becomes available. EPA will conduct the “interim review” of decaBDE when sufficient information is available. Forthcoming information that will be important to consider includes the IRIS assessment of decaBDE; the developmental neurotoxicity study being conducted for the European Union; and assessments of decaBDE environmental fate.

Activity 2.6

Text of March 2006 Project Plan

“EPA is preparing to propose a SNUR under the Toxic Substances Control Act (TSCA) for flame retardants identified as candidates for use to meet the residential upholstered furniture flammability standards under consideration by the State of California and the U.S. Consumer Product Safety Commission (CPSC). Sixteen chemical substances/categories, including decaBDE, are being considered for inclusion in the SNUR. The SNUR would require persons who intend to manufacture, import, or process any of these chemical substances, or articles containing them, for use as a flame retardant in residential upholstered furniture to notify EPA at least 90 days before commencing such activity. The required notice would provide EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit such activity before it occurs.”

Current Status

On February 1, 2008, the CPSC voted to issue a notice of proposed rulemaking on a new mandatory standard to address residential upholstered furniture fires. In a subsequent press release, CPSC stated that under the proposal, manufacturers could meet the performance standard by using smolder-resistant cover fabrics or interior fire resistant barriers to protect the furniture’s internal filling material, which is the primary fuel in an upholstered furniture fire. CPSC’s objective is to reduce the fire risk in upholstered furniture without requiring the use of fire retardant chemicals. Manufacturers will not be required to use chemicals to meet the proposed standard. In its environmental assessment, CPSC staff projects most manufacturers and importers would likely choose options that do not involve fire-retardants in fabrics or filling materials.

As a result, work on the draft proposed Significant New Use Rule (SNUR) is on hold, pending the outcome of the CPSC rulemaking.

Next Steps

EPA will evaluate the need for a SNUR when it has examined the CPSC proposed standard. If necessary, EPA will make appropriate modifications to the draft SNUR and offer the Office of Management and Budget an opportunity to review in advance of proposal.

Activity 2.7

Text of March 2006 Project Plan

“EPA’s Furniture Flame Retardancy Partnership is coordinating with the CPSC and will discuss whether to undertake a project to evaluate environmentally preferable fabric flame retardant chemicals, barrier technologies, inherently flame retardant materials and other fire safety approaches.”

Current Status

No current activity. The need for decaBDE (or other chemical flame retardants) to meet such a standard will depend on the particular option selected by CPSC – see discussion above under Activity 2.6.

Next Steps

EPA will decide whether this project is needed when it has examined the CPSC proposed standard.

Status of Activities Under Objective 3: Assess Risks of Pentabromodiphenyl Ether and Octabromodiphenyl Ether

Activity 3.1

Text of March 2006 Project Plan

“In December 2004, EPA proposed a TSCA SNUR that would require prior notice to EPA from any entity planning to begin manufacture or import of pentaBDE or octaBDE, or any of the PBDE congeners that comprise these mixtures, for any use, after January 1, 2005. EPA plans to promulgate the SNUR in 2006. The SNUR will enable EPA to review any intended future manufacture or import of pentaBDE and octaBDE. Based on health or environmental concerns that may be identified during such a review, EPA could take actions to prohibit or limit the production, processing, distribution in commerce, use, and disposal of these chemicals.”

Current Status

This activity has been completed. EPA promulgated the SNUR on June 13, 2006 (71 FR 34015). Available at: <http://www.epa.gov/oppt/pbde/>.

Next Steps

None anticipated. Further activity would be necessary only if the Agency receives a notice from an entity intending to manufacture or import pentaBDE or octaBDE.

Activity 3.2

Text of March 2006 Project Plan

“EPA will prepare a white paper that reviews and synthesizes the available information on exposure pathways for PBDEs. The purpose of this paper is to address: first, the relative importance of different pathways of exposure (i.e. food vs. house dust vs. indoor air); and second, information on how PBDEs get into various exposure media (e.g., particular foods including fish, house dust, indoor air, sediments), including migration of PBDEs from products in use and releases from disposal or incineration of products. Information on current disposal and recycling practices for end-of-life products containing PBDEs will be collected. The white paper will also identify additional studies that would be helpful to developing a better understanding of exposure pathways for PBDEs. This effort will be initiated in 2006, and the white paper will be peer reviewed in accordance with EPA’s *Peer Review Handbook* and the Office of Management and Budget’s *Final Information Quality Bulletin for Peer Review*.”

Current Status

EPA’s National Center for Environmental Assessment (NCEA) is preparing a report on assessing exposure to PBDEs. The chapters are:

- 1 – Introduction;
- 2 – Production and Use;
- 3 – Environmental Fate;
- 4 – Environmental and Exposure Media Concentrations; and
- 5 – Human Exposure.

Chapters 4 and 5 most directly address the subject of this White Paper as proposed in the Project Plan. A survey of the literature on exposure media concentrations for key PBDE congeners is presented in draft Chapter 4. These are combined with exposure factors for several pathways (inhalation, dust ingestion, food ingestion, etc.) in draft Chapter 5 to estimate an intake of PBDEs for adults and different age ranges of children, including infants. Then, a simple pharmacokinetic model converts intake doses to lipid concentrations, which are compared to measured concentrations in the literature. Key observations about exposure pathways, specific congeners, and uncertainties/data gaps are made. An article based on draft Chapters 4/5 is available:

Lorber, M (2008). Exposure of Americans to polybrominated diphenyl ethers. *Journal of Exposure Science and Environmental Epidemiology* 18(1):2-19.

<http://www.nature.com/jes/journal/v18/n1/abs/7500572a.html>

Research has suggested that house dust may be a substantial contributor to PBDE exposure. To further examine exposure pathway issues, EPA and the USDA are collaborating on a study of the bioavailability of PBDEs in house dust.

Next Steps

A completed draft document, including all 5 chapters, is expected to be circulated for internal EPA review in Spring 2008. Following internal review and clearance, EPA will initiate an external review with the intent to finalize and publish this as an EPA report. The goal is to finalize and release the document by the end of 2008.

Activity 3.3

Text of March 2006 Project Plan

“EPA is conducting a review of the available toxicology data for tetra-, penta- and hexaBDE congeners under its IRIS program. Completion of these assessments is projected for 2006.”

Current Status

The draft IRIS Toxicological Reviews for the tetraBDE-47, pentaBDE-99 and hexaBDE-153 congeners were released for public comment in December 2006, and are available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=161970>. External peer review of the Toxicological Reviews has been completed, and the documents are currently undergoing final revisions.

Next Steps

The final assessment documents are projected to be available on the IRIS website in Spring 2008.

Activity 3.4

Text of March 2006 Project Plan

“Through its VCCEP program, EPA has identified additional toxicity information as a data need for both pentaBDE and octaBDE. Specifically, EPA has determined that the primary data needs are two generation reproductive toxicity studies for both pentaBDE and octaBDE. EPA will work with the industry sponsor of the pentaBDE and octaBDE VCCEP assessments to address these data needs. EPA will also seek further research on the toxicity of pentaBDE and octaBDE. Through these efforts, EPA will identify and prioritize proposed additional toxicology studies of individual PBDE congeners and/or PBDE mixtures common in human samples. EPA will consider developing a proposal for NTP to conduct a set of tests to better characterize the toxicology of several individual PBDE congeners.”

Current Status

No current activity identified. The industry sponsors declined to conduct the recommended testing for the VCCEP Tier 2 assessment. Several toxicological studies of PBDEs, particularly BDE-47, have been published over the past year.

Next Steps

EPA will continue to monitor the developing toxicological literature on pentaBDE, octaBDE and their constituent congeners, as well as trends in environmental levels and human body burdens, to inform any decisions about whether to seek testing by the National Toxicology Program (NTP) or by other means.

Activity 3.5

Text of March 2006 Project Plan

“EPA will conduct an interim review of all available scientific information concerning pentaBDE and octaBDE in 2006/2007. The information in this review will include CDC data on PBDE body burdens in the U.S. population, data from EPA’s National Lake Fish Tissue Study, NTP studies of pentaBDE toxicology, and other studies that may become available concerning toxicology and environmental fate of PBDEs (including studies conducted or funded by EPA and other agencies listed in Appendices C and D). Based on this interim review, EPA will consider whether the information warrants pursuing additional activities, which could include:

- initiating further studies of exposure levels, exposure pathways, and/or toxicology of PBDEs.
- conducting a risk assessment of pentaBDE, octaBDE, or selected congeners. A risk assessment of these chemicals would include a review of the hazards, a dose-response evaluation, an exposure assessment, and a risk characterization.
- activities to reduce potential exposures to lower-brominated PBDE congeners.”

Current Status

EPA has continued gathering and reviewing information on pentaBDE and octaBDE, including the IRIS assessments, analysis of exposure pathways, and work being conducted internationally.

Next Steps

EPA will continue reviewing information on pentaBDE and octaBDE as it becomes available, including the body burden data now available from NHANES, several recently-published toxicology and epidemiology studies, and other relevant data. EPA will conduct the “interim review” of pentaBDE and octaBDE when sufficient information is available. Forthcoming information that will be important to consider includes the IRIS assessments of BDES 47, 99 and 153; trend data from NHANES on human body burdens; and trends in environmental measurements.

Status of Activities Under Objective 4: Track Developments Concerning Other Brominated Flame Retardants of Interest

Activity 4.1

Text of March 2006 Project Plan

“Any new flame retardants not already in commerce in the U.S. must be submitted to EPA for a premanufacture review under TSCA. During the review period, EPA may take action to prohibit or limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns. EPA will continue to scrutinize new flame retardants proposed for manufacture and import into the U.S. market and, where appropriate, will seek control measures and/or development of additional data on such chemicals by their manufacturers under TSCA Section 5 authorities.”

Current Status

Premanufacture reviews are conducted on an as-needed basis whenever EPA receives a Premanufacture Notice for a new flame retardant.

Next Steps

Conduct review as-needed.

Activity 4.2

Text of March 2006 Project Plan

“EPA will monitor the developing science on brominated flame retardants, including TBBPA and HBCD. Among the important activities underway are studies of TBBPA and HBCD as part of the European Commission FIRE project. EPA will also monitor information on disposal and recycling practices for end-of-life consumer products containing flame retardant chemicals. EPA will review the available information on other brominated flame retardants in 2006/2007. Based on this review, EPA will consider whether the information warrants pursuing additional activities, which could include initiating additional studies of environmental fate, exposure pathways, and/or toxicology of certain flame retardant chemicals, and conducting IRIS assessments of hazard and dose-response, and/or full risk assessments of certain flame retardant chemicals.”

Current Status

EPA has formed a multi-stakeholder partnership to evaluate flame retardants in printed circuit boards. Tetrabromobisphenol A (TBBPA) is currently the primary flame retardant used for this application. The partnership has identified seven specific flame retardants and fillers used in the leading alternative laminate materials. This flame retardants assessment is similar to the pentaBDE alternatives assessment conducted under Activity 1.1, but also focuses on end-of life issues (e.g. electronics

waste disposal, such as incineration or burning). Draft toxicological assessments of flame retardant chemicals in printed circuit boards are complete.

Next Steps

The draft flame retardant toxicological assessments report will be available on EPA's website for public comment in Spring 2008 and will be finalized in Fall 2008. Combustion testing on alternative laminate materials will be conducted under the sponsorship of the industry participants in the partnership by mid-2008. EPA will provide analytical support to this effort and will produce an addendum to the partnership report in late 2008.